

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 32-58 are pending in the application. Support for the new claims may be found generally throughout the specification and in the original claims. In particular, support for the claimed invention may be found in the present specification at page 1, lines 1-5; page 6, fourth full paragraph; page 7, eighth full paragraph; page 9, third full paragraph; page 10, line 3 to page 11, line 11; and page 11, fifth full paragraph. Claims 1-31 have been canceled.

In the outstanding Official Action, claims 2-3, 12-14 and 23 were rejected under 35 USC §112, second paragraph, for allegedly being indefinite. However, as noted above, claims 1-31 have been canceled. New claims 32-58 have been added. Applicant believes that claims 32-58 have been drafted in manner so as to avoid the issues raised by the Examiner.

Claims 1-4, 8-9, 11-15, 19-20, 22-24, 28-29 and 31 were rejected under 35 USC §102(b) as allegedly being anticipated by GARIBALDI. This rejection is respectfully traversed.

GARIBALDI discloses a magnetic embolic agent for magnetic placement in a vascular defect that utilizes biocompatible polymer, solvent, adhesive, and magnetic particles.

The magnetic particulates/particles are essential for the magnetic embolic agent to function.

The nature of the applied biocompatible polymer is not discussed in detail (col. 11, lines 6-42). Rather, GARIBALDI discusses that polyurethanes in general may be used. There is no suggestion or hint in GARIBALDI of using polyurethane or the amount of polyurethane to fill or short-circuit a vascular cavity as claimed. There is no recognition in GARIBALDI of using solvent or the amount of solvent as claimed.

Indeed, GARIBALDI even teaches using the solvents and biopolymers "sparingly" so as to have just enough to wet the magnetic particles (col. 13, lines 45-52).

Thus, in view of the above, applicant believes that GARIBALDI et al. fail to anticipate the claimed invention.

Claims 1-3, 5-10, 12-14, and 16-21 were rejected under 35 USC §102(b) as allegedly being anticipated by MARINOVIC (EP 0 280 451). This rejection is respectfully traversed.

MARINOVIC discloses using polyetherurethanes as filling tissue adhesives. An adhesive sealant "is prepared by mixing two components immediately before application" (see page 3, lines 15-17 of EP 0280450 A2). The first component is a "diisocyanate polyetherurethane prepolymer" which is made from (i) a diisocyanate compound and (ii) a glycol compound as a diol component (see page 3, lines 18-24 of EP 0280450 A2). The second component is an amino compound of general formula (I) which is a

"bifunctional chain extending compound". This second component ensures the hardening or crosslinking of the final polymeric material.

In other words, the polyurethane disclosed in the MARINOVIC reference is only a starting material in the preparation of the final crosslinked polyetherurethane polymer applied in the human body and does not coincide with the claimed combination. Thus, there is no suggestion or hint in MARINOVIC of using the recited polyurethane or solvent in the claimed amounts or to fill or short-circuit a vascular cavity as claimed.

Thus, in view of the above, it is believed that MARINOVIC fails to anticipate the claimed invention.

Claims 1-31 were rejected under 35 USC §103(a) as allegedly being obvious in view of GARIBALDI in view of MARINOVIC. This rejection is respectfully traversed.

As noted above, the magnetic particulates/particles are compulsory components of the compositions of GARIBALDI, so the use of the polyurethane (polyurethane solution) *per se* (i.e. without the use of any further material to facilitate the binding of the polyurethane into the vascular cavity) is not disclosed.

In this regard, GARIBALDI teaches away from the claimed invention since GARIBALDI suggests that placing a proper binding into a cavity can be achieved by limiting the amount of polymers and solvents used and by using a specific tool, i.e. by the incorporation of a "magnetic object" into the composition which

can interact with an applied magnetic field ensuring a magnetic force which is necessary for the binding (fixation) of the biocompatible polymer.

The MARINOVIC document does not suggest using polyurethane for filling or short-circuiting vascular cavities. Without the second component, the first component cannot be hardened, i.e. it would pour out from a cavity, even if it contains magnetic particles.

Moreover, the final adhesive material of MARINOVIC has a very different utility. Namely, it is "for use as a space filling adhesive sealant in neurosurgery, otorhinolaryngological surgery and plastic reconstructive surgery" (see page 3, lines 15-17 of EP 0280450 A2), which allow rapid closure of traumatic or iatrogenic bony defects" (see page 6, lines 11-14 of EP 0280450 A2).

In view of the above, it is believed that one skilled in the art would lack the motivation to combine and modify the publications in a manner so as to obtain the claimed invention. The polyurethane applied in MARINOVIC (which is only a liquid "starting material") cannot be applied in the method disclosed by GARIBALDI et al. because it does not harden without the use of a further chain extending compound.

Indeed, applicant has unexpectedly discovered for the first time that excellent results can be achieved with the use of polyurethane (polyurethane solution) without the application of

any further solid material facilitating the binding of the polyurethane into the vascular cavity. One skilled in the art simply would not have expected that solubilized polyurethane could be used in such a manner. For example, U.S. Patent No. 6,342,207 and U.S. Application No. 2001/0024637 rely on non-soluble polyurethane systems.

The Examiner is reminded that a critical step in analyzing obviousness pursuant to 35 USC §103(a) is casting the mind back to the time of the invention, to consider the thinking of one of ordinary skill in the art, only guided by the publications and then-accepted wisdom in the field. Close adherence to this methodology is important in cases where the invention itself may prompt an Examiner to "fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." Indeed, to establish a *prima facie* case of obviousness, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *In re Kotzab*, 217 F.3d 1365, 1369-70, 55 USPQ 2d 1313, 1362 (Fed. Circ. 2000). The fact that the prior art could be so modified would not have made the modification itself obvious unless the cited publications themselves suggested the desirability of the modification. *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Circ. 1984).

In light of the lack of a motivation, suggestion or teaching of the desirability of making the claimed combination, applicant believes that the publication fails to disclose or suggest the claimed invention.

Thus, applicant believes that the proposed combination of GARIBALDI et al. in view of MARINOVIC fails to render obvious the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, applicant believes that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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